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IN THE
Supreme Court of the United States

ALBERTO R. GONZALES,
ATTORNEY GENERAL, *ET AL.*,
Petitioners,

v.

STATE OF OREGON, *ET AL.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF OF THE AMERICAN PUBLIC HEALTH ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

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Interest of *Amicus Curiae*[*]

Founded in 1872, the American Public Health Association (APHA) is the oldest, largest and most diverse organization of public health professionals in the world. The association aims to protect all Americans and their communities from preventable, serious health threats and strives to assure community-based health promotion and disease prevention activities and preventive health services are universally accessible in the United States. APHA represents a broad array of health providers, educators, environmentalists, policy-makers and health officials at all levels working both within and outside governmental organizations and educational institutions.

Based on the values of health, equity, diversity, empowerment, integrity, dignity, and knowledge for individuals and communities, APHA advocates the conditions for a healthy society, promotes the scientific and professional foundation of public health practice and policy, and supports its members in promoting and protecting environmental and community health.

In the context of treatment refusal, APHA has recognized that "to the seriously ill and infirm, death is not only a distinct possibility, but sometimes preferable to any alternative," and that health care policy "should not blindly stress the continuation of life." APHA Policy 8123: Death With Dignity. APHA does not take a position on whether Oregon's law is wise policy. APHA believes, however, that sustaining the Attorney General's Directive would adversely affect the public health and submits this brief to set forth its concerns.

Summary of Argument

Although this case arises from the Attorney General's attempt to pretermit State-level policies respecting physician-

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[*]No counsel for any party authored any part of this brief. No person or entity other than *Amicus* and its counsel made a monetary contribution toward submission of this brief, which is filed with the parties' written consent.

assisted suicide, the authority asserted would sweep much further. Underlying the Directive is a claim that Congress delegated to the Attorney General broad powers to regulate the practice of medicine – and to take action against a physician for prescribing a controlled drug in the course of a medical practice the Attorney General disapproves of, even if the practice is affirmatively authorized and closely regulated by the licensing State, and even if the grounds for objection are unrelated to the possibility that drugs will be diverted or abused.

It is not only implausible that Congress *would* vest such a power in the Attorney General – but impossible to construe the statute he points to, the Controlled Substances Act (CSA), as having conferred it. Everything about that statute attests that it was enacted to address a nationally important, but discrete public health problem: the diversion and abuse of certain drugs. And everything in the Act's text and structure confirms that the Attorney General's responsibility is confined to assuring that Congress's means of addressing the problem – a closed distribution system – would operate effectively.

The regulatory regime the Attorney General asks the Court to approve also ignores the important and conspicuous public health benefits that result from entrusting matters of medical regulation and health policy to State-level resolution. As the opinions in *Glucksberg* and *Quill* eloquently attest, this long-established allocation of decision making power is working exceptionally well with respect to the very issue that is the subject of the Directive. The text of the CSA indicates that Congress meant to preserve the benefits of State regulation, and nothing in the Act's text or structure suggests that, by recognizing the intrastate dimension of the national *drug trafficking* problem, Congress intended to establish – or permit – a system of uniform *medical practice* regulation, under the Attorney General.

The Directive – and the assertion of power underlying it – carry further public health dangers. As this Court has

recognized, *patients* are harmed when physicians are deterred from providing care in accord with their professional judgment – and the possibility of intervention by law enforcement agents has a uniquely potent distorting effect on medical practice. These deterrent effects are of special concern because inappropriate *undertreatment* with controlled drugs, and inadequate pain relief for those who are terminally ill, are recognized to be public health problems of the first order. By establishing a broad and ill-defined federal law enforcement role in fields of medical practice where there is no suggestion of drug diversion or illicit physician behavior – and no claim that States are defaulting on their closed system responsibilities – the Attorney General's construction of the statute could only impede the provision of legitimate, medically appropriate care.

Sustaining the Directive would also adversely affect the *process* by which difficult, controversial, and profound policy decisions are made. Experimentation, evidence-gathering, and persuasion at the State level and in Congress are difficult; "interpretive rules," by contrast, may issue – as this one largely did – without the involvement or even awareness of those with opposing views and those most directly affected. Given the many matters that engender comparably strong objections (and that also happen to include administration of controlled drugs) sustaining the assertion of authority here would surely make pursuit of similar administrative declarations of "illegitimacy" the first resort – and the pull and haul of the lawmaking process the Constitution contemplates, a distant second choice.

ARGUMENT

I. It Is Impossible To Construe The CSA As Vesting The Attorney General With The Broad Power Claimed

A. In Enacting The CSA, Congress Did Not Confer The Authority On Which The Directive Is Premised

Although the Directive addresses the specific practice of physicians' assisting terminally ill patients to hasten death, the power claimed would extend to *any practice* in which

controlled substances are prescribed – and would include authority to pass judgment on controversial matters of medical practice and ethics, irrespective of whether the controversy (or the Attorney General's objection) has anything to do with the use of controlled (as opposed to other) substances. Moreover, the Attorney General would be empowered to bring within the ambit of federal *criminal* law medical practices affirmatively authorized and actively supervised by the licensing State.

Not only must this assertion of authority reckon with the presumption that Congress does not intend drastically to alter the federal/State balance in matters, historically entrusted to the States, see, *e.g.*, *United States v. Bass*, 404 U.S. 336, 349 (1971); *Bates v Dow Agrosciences, LLC*, 125 S. Ct. 1788,1801 (2005), *Pegram v. Herdrich*, 530 U.S. 211, 237 (2000), but it must overcome the fundamental implausibility that Congress *would* delegate power to resolve large and momentous questions of ethical and medical legitimacy, see *SWANCC v. Army Corps of Eng'rs*, 531 U.S. 159, 172 (2001); *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120,133 (2000), let alone to an official with no recognized expertise in matters of public health or medical practice.[1]

Far from "manifesting" an intent to confer such extraordinary authority, the text and structure of the CSA rule out the construction advanced, and make clear that Congress intended a more limited, but still vital responsibility for the Attorney General: maintaining the "closed system" for

[1]In fact, the federal government rarely undertakes even to *examine* questions of such complexity and moment – let alone answer them definitively for the Nation – without involving those in fields whose knowledge and experience span a far broader range than does the Attorney General's. See, *e.g.*, Exec. Order 13,237 (Nov. 28, 2001)§ 3(a) (President's Council on Bioethics "shall include members drawn from the fields of science and medicine, law and government, philosophy and theology, and other areas of the humanities and social sciences"); see also *id.* § 2(a)(5)(c) (noting "the complex and often competing moral positions" on issues and directing Council to resist "an overriding concern to find consensus").

distributing certain drugs, H.R. Rep. 91-1444 at 6 (1970), and assuring that individuals who would subvert or undermine that system do not succeed.

Thus, instead of evincing intent to centralize authority over medical practice, the CSA includes an express disclaimer of broad preemptive effect, 21 U.S.C. § 903, and expressly affirms the States' longstanding role as regulators of medical practice within their borders. See *id.* § 802(21) (defining "practitioner" to include "a physician * * * licensed by * * * the jurisdiction in which he practices to distribute [or] dispense * * * a controlled substance in the course of professional practice"). In fact, until Congress amended the Act in 1984, the Attorney General was not even *permitted* to deny registration based on a practitioner's active, improper dispensing of controlled drugs, unless the licensing State took decisive disciplinary action (or he was convicted of a felony). See *United States v. Moore*, 423 U.S. 122, 141n.19 (1975) (registration was "a matter of right" for individual "engaged in activities involving these drugs which are authorized or permitted under State law'") (quoting H.R. Rep. 91-1444 at 23).

Nor do the statutory text and structure detract from the intuitive unlikelihood of the notion that Congress would vest *the Attorney General* (or the DEA, as designee) with authority to make plenary, nationwide judgments concerning difficult, even profound questions of medical practice "under the CSA." Rather, the statute's terms and legislative history attest to Congress's concern about the Attorney General's involvement in even mundane medical decision making. See, *e.g.*, 21 U.S.C. § 811(b) ("The recommendations of the [HHS] Secretary * * * shall be binding on the Attorney General as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance"). In the one instance when Congress authorized formulation of federal standards of "professional practice" – with respect to "the

medical treatment of * * * narcotic addition," 42 U.S.C. § 290bb – it entrusted that responsibility to the HHS [then HEW] Secretary. See H.R. Rep. 93-884 (1974) ("All decisions of a medical nature are to be made by the Secretary. Law enforcement decisions respecting the security of stocks of narcotic drugs and the maintenance of records on such drugs are to be made by the Attorney General").

Indeed, the narrow lawmaking powers Congress did confer on the Attorney General are carefully cabined. Title 21 U.S.C. § 811(a) requires that decisions to place substances on the federal schedules be made through formal rulemaking pursuant to the Administrative Procedure Act; § 811(c) specifies the eight factors that must be considered in scheduling a drug; and 21 U.S.C. § 812(b) specifies findings that must be made before he may assign a drug to a particular schedule. See generally *United States v. Touby*, 500 U.S. 160, 166 (1991).

The Attorney General nonetheless contends that the structure of the CSA supports an overarching "legitimate medical practice" limitation, and that the authority asserted here, to pass judgment on what is "legitimate" "under the CSA," is essentially the same one recognized in *Moore* (and in earlier cases sustaining convictions of physicians under predecessor statutes).

At the outset, the phrase the Attorney General most thoroughly parses and identifies as the principal source of authority for the Directive – "legitimate medical purpose" – derives from a Justice Department *regulation*, see 21 C.F.R. § 1306.04(a), not the text of the relevant *statutory* provision. Compare 21 U.S.C. § 802(21); *id.* § 829(a)-(b) (exempting prescriptions "in the course of professional practice" from the Act's reach); see *Chevron U.S.A. Inc. v. NRDC, Inc.*, 467 U.S. 837 (1984) (ambiguous language *in a statute* may be treated as a delegation by Congress of interpretive authority to the agency administering the law); but cf. *Crandon v. United States* 494 U.S. 152, 177 (1990) (Scalia, J., concurring) (for purposes of

deference, prosecutor does not "administer" the criminal statute under which she proceeds). Moreover, that regulation, by its terms, addresses only what qualifies as a "valid *prescription*," 21 C.F.R. § 1306.04(a), under the CSA – though Congress expressly provided that physicians may dispense controlled substances directly to patients *without* a written prescription. See 21 U.S.C. § 829(a), (b).[2]

But accepting, as *Moore* did, that Congress contemplated keeping "medical practice within accepted limits," 423 U.S. at 142, *in order to prevent drug trafficking*, does not establish that the statute should be construed as conferring a *plenary* power to decide that particular medical practices are not "legitimate" – and then treat as federal drug offenders doctors who prescribe controlled drugs in the course of the Attorney-General-disapproved practice.

The Court in *Moore* did not *defer* to an administrative definition of what constitutes proper medical practice: the case was a criminal prosecution, see *Crandon*; and the government assumed the burden of proof, which it carried by presenting "expert medical testimony," 505 F.2d at 426 (McKinnon, J., dissenting), that the defendant had completely abandoned his professional responsibility to his "patients." There was no claim that Moore's conduct – prescribing "some 800,000 methadone tablets" over a four-month period, 423 U.S. at 126, and charging patients "according to the number of tablets desired," *id.* at 143 – was affirmatively authorized under State [District of Columbia] law.[3]

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[2]Although *Oregon law* requires a written prescription, it cannot fairly be said that this "exception" is "not relevant here," Pet.Br.3. It highlights the unsoundness of the Attorney General's construction: if the provision were intended to authorize overruling policy choices like Oregon's, it is hard to understand why Congress would have the Attorney General's power depend on whether a State's implementing legislation required a written prescription – with States that opted *against* such a patient-protective requirement enjoying *broader* latitude. Cf. 21 U.S.C. § 903.

[3]The nature of the prosecution's evidentiary burden was not decided by

The "illegitimacy" at issue in *Moore* was the very one that Congress sought to combat in enacting the CSA: selling controlled drugs, "'primarily for the profits to be derived therefrom,'" *id.* at 135 (quoting H.R. Rep. 91-1444 at 10), to those seeking them for their prohibited properties. See *id.* at 143 (defendant "acted as a large-scale 'pusher' not as a physician"). The authority to prosecute was a necessary incident of Congress's recognition, expressed in the text of the statute, that the closed system for distributing these particular drugs would be defeated if doctors were permitted to exploit their privileged position within the system, to cater the very demand the law was enacted to suppress.

By contrast, the "illegitimacy" asserted here – and the power claimed – are untethered from the text, structure, and purposes of the statute. Although the Attorney General invokes his "ability to administer the Act's comprehensive national scheme for controlling dangerous substances," Pet.Br.14, there is no suggestion that controlled drugs prescribed in compliance with Oregon law are likely, let alone especially likely, to be diverted outside legitimate channels: given the substantial additional regulation the State imposes, the opposite is surely the case. Likewise, given that the relevant patient population is limited to individuals at an advanced stage of terminal illness, it is nearly certain that the considerations that trigger control under the statute, see 21 U.S.C. § 812(b)(2) – apply with *less* force in DWDA prescriptions than in other instances where physicians prescribe Schedule II drugs in professional practice.[4]

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this Court in *Moore*, which addressed whether a rogue doctor could be *charged* under § 841. As explained *infra*, see n.11, even if the opinion's quotation of the jury instructions could be understood as approval, those instructions were – at best – ambiguous on precisely the point the Attorney General asserts they were "clear."

[4]While the Attorney General emphasizes the frequency with which terms such as "medical use," "treatment," and "treatment with severe restrictions" appear in the subsections of § 812, the power claimed draws no distinction between substances on the various schedules or between drugs subject to "severe restrictions," *id.* § 812(b)(2)(B), and those which are not.

Likewise, notwithstanding assertions that helping terminally ill patients hasten their deaths is not a "proper use of a controlled substance," Pet.Br.11, and is illegitimate *"for purposes of the CSA,"* Pet.Br.26 (emphasis added), the Attorney General does not suggest that prescribing a controlled substance to a patient who seeks to hasten death is "illegitimate" *in the same sense* that prescribing morphine to an addict would be, see *Webb v. United States*, 249 U.S. 96 (1919). The "illegitimacy" the Attorney General identifies *has nothing to do with the particular substances prescribed* – or with the particular pharmacological characteristics of those drugs. Cf. *In re Harline*, 65 Fed. Reg. 5,665, 5,670 (Feb. 4, 2000) (noting diversity of medical opinion as to "when it is appropriate to use controlled substances in the treatment of weight control").[5] Thus, the Attorney General acknowledges that "doctors in Oregon [who] dispense substances other than those regulated under the CSA to hasten their patients' deaths," are beyond the Directive's reach, Pet.Br.43; see 21 U.S.C. § 811(b), but does not suggest any *medical* distinction between those doctors' conduct and that which the Directive governs.

Two significant conclusions follow. First, it is hard to imagine that a Congress that *opposed* physician assistance of the kind Oregon has authorized – or even one that simply intended to confer on the Attorney General the authority to regulate medical practices (for reasons unrelated to drug diversion) – would so limit his power to stop practices he has determined to be "[il]legitimate."

Treating substances interchangeably is incongruous with the Act's stringent, schedule-driven limitations on the controls the Attorney General may impose – and on whether he can impose controls at all. See *id.* § 811(b).

[5]The regulatory treatment of Marinol (Pet.Br.30) is no precedent for the power claimed here. The DEA action occurred in the context of a decision rescheduling a particular drug – determined to have "a currently accepted medical use with severe restrictions," 51 Fed. Reg. at 17,476, and, as Petitioners' Brief explains, the restriction was based on "a significant risk" particular to that drug, *id.* at 17,477, *i.e.*, that it would be widely sought on account of its chemical similarity to marijuana, a Schedule I drug.

More important, although the Directive is described as embodying a "broad consensus," Pet.Br.18, none of the authorities cited opposes the "practice" of "assisted suicide [*with controlled substances*]" – or indicates that the pharmacological properties (or legal status) of the particular drug a doctor prescribes is relevant to, let alone determinative of, the "legitimacy" of the practice Oregon authorizes. Indeed, there are strong reasons to expect that many who *oppose* the Oregon law based on conceptions about doctors' proper "role," see *id.*, would *reject* the Directive's implication: *i.e.*, that Oregon physicians who *do* so help their terminally ill patients should confine themselves to substances that do not appear on the federal schedules – even when, as a matter of professional judgment, they believe that these other medications are not in their patients' best interests.[6]

B. The Meaning of "Illegitimacy" Must Be Anchored To The Statute's Text And Purposes

Moore and other cases cited by the Attorney General establish that the meaning of "legitimacy" under the CSA should be defined – and limited – by that which *Congress* recognized as "illegitimate": doctors' "trafficking" or "pushing" drugs (or enabling others to do so). So construed, the Attorney General has all the power needed to accomplish the Act's objectives and fulfill the responsibilities Congress entrusted to him, without compromising States' power to regulate medical practice, or terminating debate and experimentation in the field of public health – or unnecessarily

[6]As the Court of Appeals observed, "controlled substances provide the best and most reliable means for terminally ill patients to painlessly take their own lives." 368 F.3d at 1123 n.5 (citing Kimsma, *Euthanasia and Euthanizing Drugs in The Netherlands*, in Drug Use in Assisted Suicide and Euthanasia 193 (Battin & Lipman eds., 1996); Farber-Langendoen & Karlawish, *Should Assisted Suicide Be Only Physician Assisted?*, Annals Internal Med., Mar. 21, 2000, at 482)). Cf. *Thompson v. Western States Med. Ctr.*, 535 U.S. 357, 374 (2002) (assuming that physicians do not prescribe "unnecessary medications").

deterring legitimate, beneficial medical practice. See *infra*.

By contrast, the Attorney General's efforts – in the Directive itself and his defense of it in this Court – to formulate a definition of medical "legitimacy" narrow enough to rule out the Oregon-sanctioned practice raises serious problems.

It would seem unrealistic in any event to expect that questions that have engaged, challenged, and divided the Nation's foremost bioethicists – and engendered "earnest and profound debate," 521 U.S. at 735, among its citizenry and health care professionals – could be settled through resort to the dictionary, see Pet.Br.18. But more troubling is the guidance that the Attorney General purports to derive from those sources. Applied literally, the cited definitions would exclude *entire fields* of professional practice – and many medical procedures that are regularly performed, with controlled substances. For example, fertility treatments and cosmetic surgery (and nontherapeutic abortions) are often found *not* to entail "the cure, alleviation, and prevention of disease * * * [or] the restoration and preservation of health," Pet.Br.19 (quoting 9 Oxford English Dictionary 549 (2d ed. 1989)).

Even worse, such dictionary definitions reflect assumptions about the "ends of medicine" that not only are controversial, but are, in important ways, a cause of what all recognize to be a serious public health problem. It is precisely because prescribing pain medication to those who are terminal ill *does not* "'restor[e] or preserv[e] health or due physical condition,'" Pet.Br.19 (quoting The Random House Dictionary of the English Language 1194 (2d ed. 1987)), that medical training, focused on curing disease, long neglected to educate physicians about palliative care. See Institute of Medicine, Approaching Death: Improving Care at the End of Life 207 (Field & Cassel, eds. 1997) ("Deficiencies in * * * education for end-of-life care reflect a medical culture that defines death as failure and ignores care for dying people as a source of professional accomplishment and personal meaning").

Defining "illegitimacy" under the CSA with reference to legal standards governing "medical necessity" in the insurance reimbursement context, see Pet.Br.42, is equally ill-considered. Reimbursement denials carry no intimation of a practice's "illegitimacy." Rather, the rules governing medical necessity – which are decidedly *non*uniform among the States, see *Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355 (2002) – more often reflect determinations that scarce funds should be first allocated to procedures needed to "restore [policyholders'] health." Of course, many doctors perform procedures despite the unavailability of third-party reimbursement.

Nor does "consensus" (Pet.Br.11) distinguish the subject matter of the Directive from other medical practices on which the Attorney General might have strong views. Even accepting that Congress was interested in suppressing State diversity, but see *infra*, there is, as explained above, *no* consensus in the medical community supporting the regime the Directive would implement – in which Oregon physicians would be permitted to "dispense substances other than those regulated under the CSA to hasten their patients' deaths," Pet.Br.35, but would be harshly penalized for prescribing a controlled substance.

Even at a higher level of generality, opinion is decidedly less one-sided than portrayed. See Whitney et al, *Views of U.S. Physicians and Members of the AMA House of Delegates on Physician-Assisted Suicide*, 16 J. Gen. Intern. Med. 290 (2001) (45% of physicians surveyed answered that physician assistance should "definitely" or "probably" be legal). And although *Glucksberg* and *Quill* made quite clear that proponents of physician assistance do not have legal tradition on their side, see Pet.Br.22 (citing *Glucksberg*, 521 U.S. at 710-719); but cf. *id.* at 716 (noting "many significant changes in state laws and in the attitudes these laws reflect"), it is jarring to see the opinions in those cases – which evinced respect for Oregon's side of the "debate" and presented the DWDA's possible implementation as a constitutionally benign development –

cited as supporting the proposition that "strik[ing] the * * * balance," *id.* at 736 (O'Connor, J., concurring), in favor of patient self-determination is facially "illegitimate."[7]

C. The 1984 Amendment Did Not Confer Power To Overrule State Policy Judgments Unrelated To Controlled Substances

Nor can Congress's 1984 amendment of the CSA (see Pet.Br.34) plausibly be construed as conferring the sweeping powers asserted by the Attorney General. First, that measure's enactment calls attention to a basic problem in the Attorney General's *principal* claim: it is not easily understood why a Legislature that intended to authorize the Attorney General to overrule affirmative State policy judgments on grounds *unrelated* to drug-diversion and abuse (via the purported "delegation" of power to judge "medical legitimacy") would have enacted a law making a State's *inaction* against an individual practitioner who was, in fact, diverting controlled drugs, binding on the Attorney General, see p.5, *supra*.

More important, the text, structure, and legislative history of the law, passed as the "Dangerous Drug Diversion Control Act," make clear that Congress intended the Attorney General to "continue to give deference to the opinions of state licensing

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[7]It bears mention that the Justice Department has elsewhere *refused* to adopt precisely the same understanding of "medical practice" that is asserted to require overruling of Oregon's judgment. Many of the same organizations whose condemnation of "physician-assisted suicide" the Directive relies upon have denounced physician involvement in administering *capital punishment* as "illegitimate" – *on the same ground, i.e.*, as contrary to the physician's role as "healer," see AMA Council on Ethical & Jud. Affairs, *Physician Participation in Capital Punishment*, 270 JAMA 365 (1993). But the Justice Department has disagreed. See 58 Fed. Reg. 4,898 (Jan. 19, 1993) (declining to bar physician participation). While there is plainly no inherent contradiction in supporting capital punishment while opposing Oregon's approach to decisional autonomy at the end of life as a *policy matter*, this inconsistency highlights that disagreement with Oregon – which does not sound in drug control or law enforcement – also does not reflect a consistently adhered-to conception of "legitimate medical practice."

authorities, S. Rep. 98-225 at 262 (1984), and that the measure was addressed at a particular "weakness" in the then-existing enforcement system, *id.* Making registration *entirely* dependent on enforcement actions by often-overburdened and slow-moving State authorities, Congress recognized, raised intolerable risks that practitioners engaged in acts inimical to federal *and* State anti-diversion policy would remain entitled, as of right, to dispense controlled substances until State regulators took action, see *id.*

II. The CSA Must Be Read As Preserving States' Role In Matters of Public Health And Medical Practice

A. Public Health Is Served By Legal Principles Allowing Experimentation And Diversity At the State Level

That "the CSA is binding federal law" (Pet.Br.41) does not cast light on the legal question actually presented here: whether States retain their historic power to regulate medical practice *up to the point* that doing so would conflict with Congress's drug control concerns, or whether the CSA endows the Attorney General with plenary power over *all* medical practice "with controlled substances," with States limited to authorizing those practices which the Attorney General does not object to.

Not only is the former construction far more sensible as a matter of text, structure and legislative intent, see 21 U.S. § 903, but it draws strong support from this Court's precedents, which (1) establish that medical regulation (and public health) has traditionally – and consistently – been a matter of State concern, see, *e.g.*, *Pegram*, 530 U.S. at 237; *Linder v. United States*, 268 U.S. 5, 18 (1925), and (2) require that federal laws be construed so as to preserve, rather than displace, State authority "in areas of traditional state regulation," unless a contrary congressional intent is manifest, *Bates*, 125 S. Ct. at 1801; *Bass*, 404 U.S. at 349 (1971); *SWANCC*, 531 U.S. at 172.

Beyond the irony of invoking the spirit of the *Lochner* dissents – which championed State autonomy and experimentation – in defense of the Directive, the Attorney

General's suggestion (Pet.Br.37, 40) that these rules are relics of a bygone constitutional era is puzzling. The States' primary role in regulating medical practice – and this Court's recognition of it – did not stop with *Linder*. See, *e.g.*, *Pegram*; *Medtronic v. Lohr*, 518 U.S. 470, 475 (1996); *Rush Prudential*, 536 U.S. at 386. Nor has this understanding been idiosyncratic to the judicial branch. See 42 U.S.C. § 1395 ("Nothing in [Medicare program] shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided"); 37 Fed. Reg. 16,503, 16,504 (1972) ("[I]t is clear that Congress did not intend the [FDA] to regulate or interfere with the practice of medicine").

And as the decisions cited above attest, it is not possible to describe the modern Court's hesitancy to enforce categorical, *constitutional* limitations on congressional power as a rejection of the legal *relevance* of the historic distribution of responsibility. Rather, doctrinal developments evidence a shift in the *means* by which respect for the Constitution's federal structure is expressed: *i.e.*, increasingly through rules of statutory interpretation, which assure that States are not divested of their historic responsibilities without evidence of an deliberate congressional decision to alter the balance. See *Bass*, 404 U.S. at 349 ("the requirement of clear statement assures that the legislature has in fact faced and intended" the consequences for federal system).[8]

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[8]There is a threshold problem with the Attorney General's attempted canon-by-canon refutation – see Pet.Br.44 (asserting inapplicability of anti-preemption presumption); *id.* at 37 (asserting inapplicability of *Gregory* rule): even if *those* rules did not govern, this Court has held (in cases not cited in Petitioners' Brief) that a construction fundamentally altering the federal-State balance – that does *not* formally preempt State law or directly regulate State governments – is *also* disfavored. See, *e.g.*, *Bass*, 404 U.S. at 349; cf. *California Retail Liquor Dealers Ass'n. v. Midcal Aluminum, Inc.*, 445 U.S. 97 (1980) (federalism concerns require antitrust exception for private anticompetitive conduct that is "clearly authorized" and "actively supervised" by State).

More important are the *reasons* why the Court has not embraced a presumption in favor of displacement. "Treat[ing] the States as * * * joint participants in the governance of the Nation," *Alden v. Maine*, 527 U.S. 706, 748 (1999), "preserves to the people numerous advantages," *Gregory v. Ashcroft*, 501 U.S. 452, 458 (1991):

> It assures a decentralized government that will be more sensitive to the diverse needs of a heterogenous society; it increases opportunity for citizen involvement in democratic processes; it allows for more innovation and experimentation in government; and it makes government more responsive by putting the States in competition for a mobile citizenry.

Id. See also *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting).[9]

Equally important, while the various federalism-based canons are not identical, neither are they, as this argument presupposes, a set of discrete, disconnected rules. There is no principled reason why an interpretation of federal law that made an Oregon law literally inoperative should be disfavored, but one which "merely" subjected individuals to criminal punishment for carrying out the State's affirmative policy judgment should raise no similar judicial caution. In "sensitive areas," *Bass*, 404 U.S. at 349, such formalisms do not usually control. See *McCulloch v. Maryland*, 19 U.S. 316, 431 (1819) ("the power to tax involves the power to destroy").

[9]One principal rationale for the trend toward restraint in constitutional adjudication – recognition of the ways in which State interests are protected through the Constitution's lawmaking process, see *Garcia v. San Antonio Metro. Transit Auth.*, 469 U.S. 528, 552 (1985); *United States v. Lopez*, 514 U.S. 549, 577 (1995) (Kennedy, J., concurring) – helps explain the more stringent clear statement rule of *SWANCC*. Although Congress is not barred entirely from delegating preemptive power to an administrative agency, see *Medtronic*, 518 U.S. at 495, Congress, not the Executive, must consider the costs to the federal system. See generally Clark, *Separation of Powers as a Safeguard of Federalism*, 79 Texas L. Rev. 1321, 1393 (2001).

This case supplies a vivid illustration of what should *not* happen in a system of government where the States' distinctive constitutional status is taken seriously – and of why the *SWANCC* rule is sound. Although the Attorney General recognizes that Congress imposed stringent procedural limitations on his power to make even minor scheduling decisions – or

These advantages fully characterize the allocation of responsibility over public health, which not only permits recognition of differences in "health needs across the nation," Hodge, *The Role of New Federalism and Public Health Law*, 12 J.L. & Health 309, 356 (1998), and the benefits of policy experimentation, see Gostin, *Public Health Theory and Practice in the Constitutional Design*, 11 Health Matrix 265, 287 (2001) – but also permits a plurality of approaches on matters where disagreement has significant moral, as well as empirical, dimensions.

B. Oregon's Law Is A Legitimate and Important Policy "Experiment"

Oregon's law exemplifies these benefits. In *Glucksberg* and *Quill*, the Court described the continuing State-level debate "about the morality, legality, and practicality of physician-assisted suicide" as a paradigm of what "should [occur] in a democratic society," 521 U.S. at 735. Justice O'Connor's opinion invoked States' "extensive and serious evaluation" as a ground for restraint on the constitutional question presented, see *id.* at 737, and Justice Souter noted that the Court's judgment would allow "experimentation [to] be attempted in some of the States," *id.* at 787, which, in turn would "confirm[] or discredit[] the concerns" about possible abuse, *id.*

Consistent with these expectations, Oregon's decision to strike a different "balance" – to serve as a "laboratory" for the "novel social * * * experiment," of regulated physician-assisted suicide, *New State Ice*, 285 U.S. at 311 – has catalyzed deliberation and action elsewhere, and its experience under the DWDA has informed the public discussion of the subject and promoted the reasoned development of public health policy.

By imposing recordkeeping requirements, see Or. Rev. Stat. § 127.855, and issuing detailed annual reports, *id.* § 127.865,

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revoke the registration of a single practitioner, he did not even give Oregon meaningful *notice* that the rule, purporting to nullify the verdict of two State referenda, was in the offing, let alone afford an opportunity to be heard.

which include demographic information about the patients who have obtained prescriptions and results of interviews with prescribing physicians concerning their patients' circumstances and reasons for requesting prescriptions, Oregon has enabled research on empirical questions that have long figured centrally in the policy debate. For example, researchers have consistently found that experience in Oregon *does not* bear out concerns that physician-assistance "would be disproportionately chosen by or forced on terminally ill patients who were poor, uneducated, uninsured, or fearful of the financial consequences of their illness." Chin et al., *Legalized Physician-Assisted Suicide in Oregon – The First Year's Experience*, 340 New Eng. J. Med. 577, 582 (1999); accord Hedberg et al., *Five Years of Legal Physician-Assisted Suicide in Oregon*, 348 New Eng. J. Med. 961 (2003).[10]

C. The Extent and Benefits of Regulatory Diversity Are Significant

The Attorney General's brief, focused narrowly on a single development in a single mode of health regulation – the eclipse of the "locality rule" in medical malpractice litigation (Pet.Br.36), but see p. 21, *infra* – does not begin to capture the extent and importance of ongoing State-level innovation, experimentation, and diversity in health law and policy.

Professional licensure laws continue to reflect substantial interstate differences: "Arizona recognizes and licenses the professions of chiropractic, acupuncture, naturopathy, and homeopathy. The States of Oregon and Utah recognize and license practitioners of chiropractic, acupuncture, and

[10]Research has also cast doubt on predictions that the Act's implementation would adversely affect other aspects of health care for the dying, finding, for example, that a high proportion of Oregon doctors had made efforts to improve their knowledge of pain medications and their recognition of depression and other psychiatric disorders, and were referring more patients to hospice care. See Ganzini et al., *Oregon Physicians' Attitudes About and Experiences With End-of-Life Care Since The Passage of the Oregon Death With Dignity Act*, 285 JAMA 2363 (2001).

naturopathy. The States of Alabama, Illinois, Indiana, Michigan, Minnesota, Mississippi, North Carolina, Oklahoma, South Dakota, and Wyoming, recognize and license only physicians, surgeons and chiropractors." Cohen, *Holistic Health Care: Including Alternative and Complementary Medicine In Insurance and Regulatory Schemes*, 38 Ariz. L. Rev 83 (1996). Midwifery is prohibited in 14 States and the District of Columbia, see http://www.mana.org/statechart.html, while 10 of the 36 States that permit it provide for Medicaid reimbursement.

On the other hand, experiences in "vanguard" States have influenced important changes in the mainstream. For example, acupuncture, once marginalized, has been shown to be effective enough for the National Institutes of Health to call for its expanded use in "conventional medicine," *Acupuncture: NIH Consensus Statement* 15(5):1-34 (1997); compare *Acupuncture as Illegal Practice of Medicine*, 72 A.L.R.3d 1257 (1976).

In some health areas, a single State's innovative policy will meet with rapid acceptance. In 1997, Florida, recognizing the life-saving benefits of defibrillators for people suffering cardiac arrest, was the first State to enact a law broadly encouraging public access to such devices. By mid-2001, all fifty States had adopted similar measures. See http://www.ncsl.org/programs/health/aed.htm. By contrast, other controversial medical practice questions have divided the States for decades. See, *e.g.*, Cohen, 38 Ariz. L. Rev. at 117 (discussing differing States' responses to EDTA chelation treatment).

States have played the central role in fighting emergent health threats, most prominently the HIV epidemic, see Carson et al., *The Impact of Laws on HIV and STD Prevention*, 30 J. L. Med. Eth. 139 (2002), staking out significantly different, often controversial, policy approaches. Compare *id.* at 141 (asserting health benefits of "name-based reporting") with Schwartz, *Where Everybody Knows Your Name: Iowa's Policy of Name-Based HIV Reporting*, 7 J. Race & Gender Just. 387 (2003)

(criticizing such policies on public health grounds).

And States have likewise taken nonuniform approaches to important developments in reproductive medicine, see Nat'l Conf. State Legislatures, *50-State Summary of Laws Related To Insurance Coverage for Infertility Therapy* (describing States' regulation of in-vitro-fertilization); see also http://www.ec-help.org (noting that six States permit women to obtain emergency contraception directly from pharmacies).

The impassioned, ongoing debate over stem cell research have led some States to enact prohibitions on the practice of "therapeutic cloning," while two have passed laws affirmatively encouraging it. Compare, *e.g.*, N.D. Cent. Code § 12.1-39; Mich. Comp. Laws § 333.16274 with Cal. Health & Safety Code §§ 24185, 125300; N.J. Stat. § 26:2Z-2.

Finally, as *Glucksberg* recognized, 521 U.S. at 716, States have played a primary, dynamic – but not monolithic – role in addressing the legal, ethical, and medical issues involving end-of-life care and decisionmaking, cf. 42 U.S.C. § 1395cc(f). And they are playing an important role in responding to developments in pain medicine and in addressing documented problems of inappropriate undertreatment. See, *e.g.*, Tarzian, *Achieving the Right Balance in Oversight of Physician Opioid Prescribing for Pain: The Role of State Medical Boards* 31 J.L. Med. & Ethics 21, 23 (2003) ("In 1999, the Oregon Medical Board was the first in the nation to discipline a physician for failure to prescribe adequate pain relief medication").

D. Congress Did Not Intend The CSA To Standardize Medical Practice Nationwide

While the Attorney General insists that Congress should be "presumed" to have intended to standardize medical practice (with controlled substances) throughout the United States, the mere fact that the CSA is national in scope (and paramount in cases of "positive conflict" with State law) does not mean that Congress intended to broadly repudiate this beneficial State nonuniformity, see *Hillsborough County v. Automated Med.*

Labs., Inc., 471 U.S. 707, 719 (1985) (that "every subject that merits congressional legislation is, by definition, a subject of national concern [does not] * * * * mean * * * that every federal statute ousts all related state law"), and the CSA's textual indications are plainly "to the contrary," *Mississippi Band of Choctaw Indians v. Holyfield*, 490 U.S. 30, 43 (1989).

As a matter of law and fact, the Act contemplates extensive variation in medical practice from State-to-State, and expressly references State law in both the key definitional section, 21 U.S.C. § 802(21), and the other provision the Attorney General invokes, *id.* § 823(f). Indeed, even the provisions cited as evidence of an intent to impose uniformity support the opposite conclusion. Thus, the 1984 amendment, while denying dispositive effect to State nonenforcement, contemplated that "deference" to State decision making would remain the norm, see p.13, *supra*. And while the Act's drug treatment provisions, see Pet.Br.33, *do* contemplate federally-formulated standards "of professional practice" in that one area, such an express and specific indication argues *against* treating silence in the rest of the Act as a broad mandate for national standards. Indeed, that specific authority involves a field of practice, dispensing scheduled drugs to drug-dependent patients, where the statute's core concerns are uniquely implicated – and even then, Congress took care to *limit* the Attorney General's role in *medical* decisionmaking, see p.6, *supra*.

Nor is there any tension between preserving State authority over medical practice and the trend away from the "locality rule" in medical malpractice lawsuits (Pet.Br.36). As explained above, malpractice law represents a single strand of State health care regulation – and, three decades after the CSA, there remains substantial diversity among States even in that field. Cf. *Rush Prudential*, 536 U.S. at 386 ("standards of reasonable medical care" are "quintessentially state-law" matters); *BMW N. America v. Gore*, 517 U.S. 559, 615 (1996) (Ginsburg, J., dissenting). And this development's significance is readily

overstated: many jurisdictions that no longer require injured plaintiffs to produce testimony of local *expert witnesses*, see M. Boumil & C. Elias, The Law of Medical Liability 30 (1995), continue to adhere to the "respected minority" doctrine – under which liability may *not* be imposed for noncompliance with the predominant view of proper practice, if the conduct is supported by any "competent medical authority, subscribed to by reputable, respectable and reasonable medical experts * * * in the field," *Tobash v. Jones*, 213 A.2d 588, 592 (Pa. 1965).

The Attorney General's other policy argument – that nonuniform standards of medical practice hamper prosecution of rogue doctors – is largely beside the point. For the reasons explained in Part I, even if it were clear that a single federal standard applied in cases charging doctors with "large scale drug trafficking," that would *not* establish the necessity or desirability of – let alone a congressional preference for – national uniformity as to the "legitimacy" of *every* medical practice that happened to involve controlled substances.

But even on that limited point, the case for national uniformity is not airtight. There does not seem much basis for concern that a jury would *acquit* a doctor, proved by the government to be selling drugs in contravention of widely accepted standards, based solely on the defendant's "own view," Pet.Br.35, of acceptable State practice. Cf. *Tesauro v. Perrige*, 650 A.2d 1079, 1082 (Pa. Super. Ct. 1994) (malpractice defendant bears burden of producing "adequate factual support for his claim that there are a considerable number of professionals who agree with the treatment"). By the same token, it is not obvious that a jury instructed as were those in the cases cited approvingly in the Attorney General's brief (Pet.Br.31) would *convict* a physician, in the rare instance where his conduct strictly complied with a "state statutory law governing the particular matter in question," *id.* at 35; in such an instance, it presumably would be hard for the Government to carry its burden of proving that the physician was not acting

"in good faith," see, *e.g.*, *United States v. Rosenberg*, 515 F.2d 190, 198 (9th Cir.1975), and there would be strong arguments against mounting a prosecution at all.[11]

Nor do the Court's recent decisions in "medical marijuana" cases support construing the CSA as enacting a national medical practice regulation – or a preemptive ban on assisted suicide. First, the legal issue presented here is nothing like the one decided in *United States v. Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483 (2001) ("*OCBC*"), which held that a federal court's recognition of a "medical necessity" defense to a marijuana distribution charge would be precluded by the statutory determination that that the drug has *no* "accepted medical use." See *id.* at 483; cf. *Moore*, 423 U.S. at 142 (authority "under the CSA to dispense * * * Schedule I drugs * * * does not follow automatically from state registration as it does with respect to drugs in Schedules II through V, all of which have some accepted medical use"). *OCBC* recognized that a State law that purported to overrule the federal ban on distribution of marijuana would not only be in "positive conflict," 21 U.S.C. § 903, with that drug's placement on Schedule I, but also in tension with the statutory structure, which relies on centralized scheduling decisions, guided by

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[11]However rare such situations may be, Pet.Br.35, the exercise of power at issue here obviously *does* entail overruling "state statutory law governing the particular matter in question," *id.*

The question actually presented in *Moore* was whether a physician could ever be prosecuted under § 841 – not the standard for establishing guilt – but it is not at all "clear that Moore's conviction * * * was based on a uniform nationwide standard" (Pet. Br.31). As quoted in the opinion, the jury instruction directed that compliance "with *a* standard of medical practice generally recognized and accepted in the United States," 423 U.S. at 139 (emphasis added), would preclude conviction; and "the jury was instructed that Dr. Moore could not be convicted if he merely made 'an honest effort' to prescribe for detoxification in compliance with *an* accepted standard of medical practice," *id.* at 143 n.20 (emphasis added); see also *id.* at 126 ("The Government's position [was] that Dr. Moore's conduct was inconsistent with *all* accepted methods of treating addicts").

specific congressionally-identified factors, to determine whether – and subject to which controls – a substance may be distributed.[12]

Here, there is no "positive conflict" – or even implied conflict – between Oregon's exercise of its historic powers and *any* congressional determination, let alone any affront to the scheme of substance-based scheduling and controls that Congress enacted. This case does not involve enforcement of a federal prohibition "duplicative" of or "parallel" to a repealed State law, see Pet.Br.44: the Attorney General effectively claims power under the CSA *to create* a crime of "assisted-suicide [with a controlled substance]."[13]

III. Sustaining The Assertion of Authority Would Interfere With Proper Health Care

There are important public health reasons why even the powers Congress *did* confer on the Attorney General must be clearly and narrowly defined and sensitively exercised. As Congress, this Court, and others have often recognized, *patients*

[12]The suggestion (Pet.Br.29) that *OCBC* recognized the Attorney General's power to displace State laws to be *greater* than Congress's misreads the decision. Respondents in *OCBC* did *not* claim that the Attorney General had especially broad power under the CSA; their contention, rejected in the relevant opinion passage, was that because the mandatory § 812(b) criteria are binding only in an *administrative* scheduling, Congress's placement of marijuana on schedule I did not *literally* establish – as a lawful DEA classification *necessarily* would – that the drug had been determined to "lack accepted medical use."

[13]*Gonzales v. Raich*, 125 S. Ct. 2197 (2005), which addressed Congress's power *under the Constitution* to regulate intrastate marijuana possession for medical purposes, is of no more help to the Attorney General – and even less relevant. That decision proceeded from the premise that Congress had *in fact* prohibited Respondents' conduct by enacting the CSA, and then held that the decision to do so – supported by unquestioned power over interstate trafficking in marijuana and by findings that regulation of local activity was necessary to make the national prohibition effective – were within its Article I power. Cf. *New State Ice*, 285 U.S. at 311 (Brandeis, J., dissenting) (emphasizing value of State experimentation that poses no "risk to the rest of the country").

are ill-served when their doctors are deterred from practicing medicine in accordance with professional judgment – or from providing care at all. See *Moore*, 423 U.S. at 143 (noting presidential commission findings that "'fear of prosecution" leads "many physicians [to] * * * shun addicts as patients" or provide them inappropriate care); *Conant v. Walters*, 309 F.3d 629, 640 n.2 (9th Cir. 2002) (Kozinski, J., concurring) ("'[P]hysicians are particularly easily deterred by the threat of governmental investigation and/or sanction from engaging in conduct that is entirely lawful and medically appropriate'") (quoting expert report); cf. *Thompson*, 535 U.S. at 374 (recognizing benefits to patients of permitting physicians to prescribe compounded drugs and "off-label" uses).

The dangers of such deterrence are especially acute where controlled substances are involved. Not only does prescribing such medications subject the practitioner to far greater governmental scrutiny (heightening concerns about possible investigations and enforcement actions, see *infra*), but many individual physicians, like the rest of society, harbor inaccurate assumptions about the risks such drugs pose, see Oken, *Curing Healthcare Providers' Failure to Administer Opiods in the Treatment of Severe Pain*, 23 Cardozo L. Rev. 1917, 1938 (2002); Morgan, *American Opiophobia: A Customary Underutilization of Opioid Analgesics*, in Controversies in Alcoholism and Substance Abuse (Stimmel, ed. 1986) at 171, and professional training historically did not treat their principal benefit – relieving patients' pain – as an important part of doctors' medical treatment responsibilities, see p. 10, *supra*.

For these reasons, the Directive and the construction of the Act on which it rests – which would grant the Attorney General broad and ill-defined power to investigate, discipline, and prosecute doctors for actions taken in good faith, in accord with professional judgment and State law, in situations where there is not even a suggestion of drug diversion – represent, from a public health perspective, a long step in the wrong direction.

A. The Directive Will Worsen Existing, Serious Inadequacies in End-of-Life Care

Both in Oregon and elsewhere, the Directive would negatively affect care in a field of medical practice – care for the terminally ill – in which legitimate concerns about drug diversion and addiction are at their nadir, and in which very serious inadequacies have already widely recognized.

As noted above, see p. 9, *supra*, the Directive's operation *in Oregon* would be troubling even on its own terms. Because it is limited to controlled substances, see § 811(b); Pet.Br.43, the Directive apparently would not stand in the way of Oregon physicians' pursuing the objected-to "aim[]" (Pet.Br.19), by means that the physician does not believe – and the Attorney General does not suggest – are more *medically* appropriate.[14]

The Directive's most serious adverse effects, however, would be in jurisdictions where traditional bans remain in effect. Notwithstanding the oblique assertion that increased enforcement activity outside Oregon is not "portend[ed]," the Directive plainly declares an intention to regulate end-of-life care throughout the Nation, *i.e.*, "regardless of whether state law authorizes or permits [assisting suicide] by practitioners or others and regardless of the condition of the person whose suicide is assisted," 66 Fed. Reg. at 56,608, threatening physicians who provide "illegitimate" assistance to terminally ill patients with "the penalties provided for violations of * * * law relating to controlled substances," 21 C.F.R. § 1306.04(a).

The impact of this unprecedented assertion of authority

[14]To the extent that the Directive is intended to dissuade *States* otherwise inclined to follow Oregon's course from doing so, its implications are also potentially perverse. In view of evidence that physician assistance occurs throughout the country, see Meier et al, *A National Survey of Physician-Assisted Suicide and Euthanasia in the United States*, 338 N. Eng. J. Med. 1193 (2001), the Directive would give jurisdictions where the practice is tacitly accepted (but legally prohibited) strong incentive to remain beneath the Attorney General's "radar" – thereby denying patients the formal safeguards and public scrutiny that formal regimes like Oregon's provide.

must be understood in light of the already serious problem it would aggravate – inadequate palliative care for the terminally ill. Even absent the Directive, "[t]oo many dying people suffer from pain * * * that clinicians could * * * relieve with existing * * * therapies." Approaching Death at 2. The consensus view across a variety of disciplines is that undertreatment of pain is a pervasive public health problem. See Martino, *In Search of a New Ethic for Treating Patients with Chronic Pain: What Can Medical Boards Do?*, 26 J.L. Med. & Ethics 332 (1998).[15]

As courts and researchers have recognized, this phenomenon is not primarily explained by a lack of available medications – or by "legal barriers to obtaining medication * * * to alleviate * * * suffering," *Glucksberg*, 521 U.S. at 736-37 (O'Connor, J., concurring), so much as by "reluctance of health care practitioners to use narcotic analgesics fully for therapeutic purposes." Martino, 26 J.L. Med. & Ethics at 333. As noted, see p. 25, *supra*, this reluctance is partly attributable to a professional culture that long neglected the importance of palliative care – and to doctors' own misconceptions about drug dependence – but it is significantly driven by apprehensions about the prospect of governmental investigation, legal sanctions, and the attendant professional stigma.[16]

[15]Studies have found that 41.2% of the 2.2 million residents of U.S. nursing homes have "persistent pain," Teno et al., *Persistent Pain in Nursing Home Residents*, 285 JAMA 2081 (2001); that large percentages of terminally ill patients spend their last days in moderate to severe pain, see *A Controlled Trial to Improve Care for Seriously Ill Hospitalized Patients*, 274 JAMA 1591 (1995); that significant numbers of elderly cancer patients in nursing homes received no analgesics at all, Bernabei et al., *Management of Pain in Elderly Patients with Cancer*, 279 JAMA 1877 (1998); and that minority patients are at special risk of undertreatment, see Cleeland et al., *Pain Management in Minority Patients With Cancer*, 127 Annals Internal Med. 813 (1997); see also Von Roenn et al., *Physician Attitudes and Practices in Cancer Pain Management*, 119 Annals Internal Med. 121 (1993) (86% of physicians responded that the majority of cancer patients with pain were undermedicated).

[16]See, *e.g.*, Sabatino, *Removing Legal Obstacles to Effective Pain Management*, NAELA Q., Spring 2001, at 15, 19; Johnson, *Disciplinary*

Cases involving the terminally ill present special challenges, because drugs, if applied in certain dosages, can hasten death: "The threat of prosecution, the possibility of being labeled another Kevorkian, and the risk of losing prescribing or practice privileges are all strong incentives to say no, even in instances where the use of high doses of opioids is not only the legitimate, but also the most humane course of action," Martino, 26 J.L. Med. & Ethics at 337; see Haugen, *Pain Relief for the Dying: The Unwelcome Intervention of the Criminal Law*, 23 Wm. Mitchell L. Rev. 325 (1997); Kapp, *Treating Medical Charts Near the End of Life: How Legal Anxieties Inhibit Good Patient Deaths*, 28 U. Tol. L. Rev. 521 (1997).

Even though the Directive includes language professing recognition of the "important medical, ethical, and legal distinctions between intentionally causing a patient's death and providing sufficient dosages of pain medication necessary to eliminate or alleviate pain," 66 Fed. Reg. at 56,608, it can only aggravate these concerns. That language falls conspicuously short of recognizing a safe harbor (as some State laws have) for prescribing drugs that have the "double effect" of hastening death, see *Glucksberg*, 521 U.S. at 780 n.15 (Souter, J., concurring); indeed, nothing in the Directive indicates that the Attorney General would not investigate a physician who was in compliance with his or her State's provision. Even in those jurisdictions, physicians fearful of having their "intent" misread may refrain from administering (appropriately) high doses of pain medication to their terminally ill patients. See Groopman, *Separating Death From Agony*, N.Y. Times, Nov. 9, 2001, at A21 (describing as "medically impossible" to "dissociate intentionally ameliorating a dying patient's agony from intentionally shortening the time left to live").

Actions and Pain Relief: An Analysis of the Pain Relief Act, 24 J.L. Med. & Ethics 319, 320 (1996); Hill, *Government Regulatory Influences on Opioid Prescribing and Their Impact on the Treatment of Pain of Nonmalignant Origin*, 11 J. Pain & Symptom Mgmt. 287, 288 (1996).

The Directive would increase these deterrents vastly, by vesting medically untrained law enforcement agents with authority to ascertain a physician's "motive" in caring for a deceased patient; by raising the stakes of such investigations; and by heightening the danger that those making such inherently delicate judgments would apply conflicting standards.

B. The Authority Claimed, If Approved, Would Chill Legitimate Medical Practice And Distort the Process By Which Controversial Policy Questions Are Resolved

Sustaining the Attorney General's construction of the statute would not merely affect the subject matter of the *Directive*, but would enable a federal law enforcement presence in matters, far removed from the concerns that led to enactment of the CSA, that have always been for State resolution.

The construction of the statute advanced in this Court would also authorize actions against doctors for prescribing pain medication for patients who are *not* terminally ill, even when done in full, good faith compliance with "*state statutory law governing the particular matter in question*." Pet.Br.35 (emphasis added). As researchers have found, the tendency to undertreat severe pain of those *not* in the late stages of terminal disease is likely a more pervasive – and harder to solve – problem than is inadequate care at the end of life.[17]

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[17]Not only has end-of-life care received more focused policy attention, but many doctors' reluctance to prescribe potentially dependency-inducing medication is especially pronounced for patients with chronic pain, and the standards of proper care for management of such pain are less well-established. See Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Clinicians' Perspective*, 24 J.L. Med. & Ethics 296 (1996); Davidson, *Pain and Opiophobia*, 40 Healthcare Forum J. 64 (1997); Hyman, *Pain Management and Disciplinary Action: How Medical Boards Can Remove Barriers to Effective Treatment*, 24 J.L. Med. & Ethics 338 (1996). See Federation of State Medical Boards of the United States, *Model Policy for the Use of Controlled Substances for the Treatment of Pain* (2004) (recognizing undertreatment of pain to be a "serious public health problem" and citing doctors' "perception that prescribing adequate amounts of

Moreover, as explained above (pp. 10-11), the Attorney General's efforts to articulate a definition of "illegitimacy" not limited to "closed system" concerns would bring prescription of controlled substances in the course of *any* experimental or nontherapeutic medical procedure within the ambit of the CSA – with the Attorney General's available grounds for proceeding against a doctor (or overruling a State) not limited to reasons of drug control or even medical appropriateness.

It is no answer that the Attorney General might not attempt such further assertions of power. First, as just described, the threat of *conviction* is not needed to distort doctors' choices – in ways that disserve patients (and the Directive itself would hardly have been a foreseeable development from the vantage point of *Glucksberg* and *Quill*). But whether or not similar "interpretive rules" were ultimately to issue, the process for resolving difficult questions of policy and morality would be skewed, encouraging those who object to novel and controversial practices to bypass State-level (and even congressional) debate and ask the Attorney General to "stay experimentation" at the earliest possible stage (when a fully contrary "consensus" could most plausibly be claimed).

Such a regime would be inimical to the public health, and it is not what should happen in "a democratic society," *Glucksberg*, 521 U.S. at 735.

Conclusion

The judgment of the Court of Appeals should be affirmed.

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controlled substances will result in unnecessary scrutiny by regulatory authorities" as a contributing cause).

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